Medical Device Alert

Ref: MDA/2013/019 Issued: 27 March 2013 at 13:00

Device

Detergent and disinfectant wipes used on reusable medical devices with plastic surfaces.

All manufacturers.

Problem

Detergent and disinfectant wipes can damage plastic surfaces of medical devices if they are not compatible with the surface material.

Damaged surfaces may compromise the ability to decontaminate medical devices adequately and / or may interfere with device function.

Action by

All staff involved in the decontamination of medical devices.

Action

Ensure detergent and disinfectant wipes are compatible with the device.

Always follow the device manufacturer's decontamination instructions.

Look for signs of damage to the medical device and follow local reporting procedures as appropriate.

If the manufacturer's decontamination instructions are inadequate, report this fact to the MHRA and the manufacturer.

CAS deadlines

Action underway: 25 April 2013

Action complete: 26 September 2013

Note: These deadlines are for systems to be in place and for processes and instructions to be reviewed.

Problem

The MHRA and Health Facilities Scotland have received incident reports relating to detergent and disinfectant wipes that have degraded plastic surfaces of medical devices and affected their performance and integrity. The reports describe damage to devices such as tympanic thermometers, patient monitors, infusion pumps, dialysis fluid filters, peritoneal dialysis transfer sets and infant warmers.

Failure to follow the device manufacturer's decontamination instructions may be considered off-label use. Advice relating to this can be found in the MHRA's alert **MDA/2010/001** – "Medical devices in general and non-medical products".

Action

Identify all device decontamination processes that include using a detergent and /or disinfectant wipe on a plastic surface and ensure that you have a compatible process in accordance with the device manufacturer's instructions. If in doubt contact the device manufacturer for clarification.

If you identify an incompatible process:

1. Revert to the device manufacturer's decontamination instructions.
2. Risk assess the impact on patients and take the appropriate corrective action.

Follow the advice to 'Use only chemicals compatible with the device and at the correct concentration as recommended by the various manufacturers involved' (from the MHRA's guidance document 'Managing Medical Devices').

Pre-purchase questionnaires during the procurement process may be helpful in ensuring compatibility of devices. An example can be found on the Institute of Decontamination Sciences' website at http://www.idsc-uk.co.uk/news.php (accessed 25/03/2013).

Ensure that all staff involved in decontamination processes are fully trained and that this training is regularly updated.

Report any device problems to the MHRA via our website.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- Health Protection Agency (HPA) (Directors)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- Local authorities in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Health and Safety Executive
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- All departments
- All staff
- All wards

Health Protection Agency

Directors for onward distribution to:

- Collaborating centres
- Consultants in communicable disease control
- Divisional directors
- Heads of department
- Heads of health, safety and quality
- Health protection nurses
- HPA laboratories
- Laboratory managers
- Regional microbiologists
- Risk manager
- Safety officers

Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Chiropodists
- Community children's nurses
- Community defibrillation officers
- Community dental practices
- Community diabetes specialist nurses
- Community hospitals
- Community midwives
- Community nurses
- Community optometrists
- Community pharmacists
- Dispensing opticians
- District nurses
- Equipment libraries and stores
- Health visitors
- Immunisation co-ordinators
- Infection control nurses
- Maintenance staff
- Minor injury units
- NHS walk-in centres
- Nutritional nurse specialists
- Occupational health departments
- Occupational therapists
- Optometrists
- Palliative care teams
- Physiotherapists
- Podiatrists
- Practice managers
- Practice nurses
- School nurses
- Walk-in centres

Social services

Liaison officers for onward distribution to all relevant staff including:

- Back care/manual handling advisors
- Care at home staff
- Care management team managers
- Children's disability services
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)
- Disability equipment stores
- Environmental health officers
- Equipment stores
- Equipment supplies managers
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes
- Loan store managers
- Loaned equipment store managers
- Occupational health departments
- Occupational therapists
- Schools with hoists
- Wheelchair and seating service managers

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Establishments registered with OFSTED

This alert should be read by:

- Children's services
- Educational establishments with beds for children
- Residential special schools

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/019** or **2011/011/022/081/014**

Technical aspects
John McManus or Ian Smith
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7226 / 7306
Fax: 020 8754 3965

Email: john.mcmanus@mhra.gsi.gov.uk
ian.smith@mhra.gsi.gov.uk

Clinical aspects
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Medicines & Healthcare products Regulatory Agency
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London SW1W 9SZ

Tel: 020 3080 7126
Fax: 020 8754 3965

Email: nicola.lennard@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic

Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:
Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk